

AMENDMENT AND RESPONSE TO OFFICE ACTION

Amendment

In the Claims

1. (Currently amended) A vaginal or rectal applicator comprising

(a) an applicator barrel, wherein the applicator barrel has a size and shape suitable for insertion into the vagina or rectum and suitable for preventing penetration of the vaginal wall, cervix or rectum, wherein the applicator barrel comprises a medication chamber at the proximal end of the applicator, wherein the medication chamber has a smaller diameter than the diameter of the applicator barrel and wherein the medication chamber is designed to contain up to 1 mL of a pharmaceutical composition in a form selected from the group consisting of powder, gel, cream, and lotion, wherein the proximal end of the applicator contains an opening suitable for filling the medication chamber with the pharmaceutical composition and dispensing the pharmaceutical composition from the medication chamber, and wherein the applicator barrel comprises a barrier proximal to the opening;

(b) a plunger, wherein the plunger is insertable in telescoping relation to the applicator barrel until the plunger reaches the barrier;

(c) a plunger tip, wherein the plunger tip is at the end of the plunger; and

(d) an applicator cap, wherein the applicator cap is removable from the proximal end of the applicator barrel.

2. (Original) The vaginal or rectal applicator of claim 1, wherein the applicator further comprises a flange.

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3. (Previously presented) The vaginal or rectal applicator of claim 1, wherein the applicator cap has a diameter that is effective at preventing insertion of the vaginal applicator into a vagina when the applicator cap is attached to the applicator barrel.

4. (Original) The vaginal or rectal applicator of claim 1, wherein the applicator cap forms an air-tight seal with the applicator barrel.

5. (Original) The vaginal or rectal applicator of claim 1, wherein the plunger tip forms an air-tight seal with the applicator barrel.

6. (Currently amended) A method of transvaginal or transrectal drug delivery comprising

(1) breech filling a vaginal or rectal applicator with 1 mL or less of a pharmaceutical formulation in a vaginal or rectal applicator, wherein the vaginal applicator comprises

(a) an applicator barrel, wherein the applicator barrel has a size and shape suitable for insertion into the vagina or rectum and suitable for preventing penetration of the vaginal wall, cervix or rectum, wherein the applicator barrel comprises a medication chamber at the proximal end of the applicator, wherein the medication chamber has a smaller diameter than the diameter of the applicator barrel, wherein the medication chamber is designed to contain up to 1 mL of a pharmaceutical composition and wherein the applicator barrel comprises a barrier proximal to the opening;

(b) a plunger, wherein the plunger is insertable in telescoping relation to the applicator barrel until the plunger reaches the barrier; and

(c) a plunger tip, wherein the plunger tip is at the end of the plunger;
(2) placing an applicator cap on the applicator barrel;

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(3) removing the applicator cap from the proximal end of the applicator barrel; and
(4) (2) inserting the applicator barrel into a patient's vagina or rectum,
wherein the pharmaceutical formulation is in a form selected from the group consisting of
a powder, gel, cream, and lotion.

7. (Canceled).

8. (Original) The method of claim 6, further comprising depressing the plunger to
administer the pharmaceutical formulation to the region of the patient's upper vaginal vault or
rectum.

9. (Previously presented) The method of claim 6, wherein the pharmaceutical
formulation is in an amount effective to treat disorders and diseases of the female urogenital
system, cervix, uterus, ovaries, fallopian tubes, peritoneal cavity, and lower abdominal cavity.

10. (Previously presented) The method of claim 6, further comprising depressing the
plunger until it reaches the barrier.

11. (New) The method of claim 6, further comprising, after step (1) and prior to step (2),
placing an applicator cap on the proximal end of the applicator barrel and then removing the
applicator cap from the proximal end of the applicator barrel.